

Claim 1.(Amended) A one-piece sterile [disposable dispenser for the irrigation and debriding of wounds and incisions] wound irrigation and debriding system, which is disposable in any container, comprising:

a flexible chamber having an internal volume containing a sterile solution, said chamber having an orifice at one end thereof;

a nozzle having a first opening at one end and a second opening at the other end thereof, wherein said first opening is affixed to said orifice of said chamber; and said second opening dispenses said solution;

a protective tip affixed to said second opening of said nozzle, thereby maintaining said solution in a sterile state; and

a removable packaging band around said protective tip.

In Claim 2, delete "dispenser" and replace it with the phrase -- wound irrigation and debriding system --.

In Claim 3, delete "dispenser" and replace it with the phrase -- wound irrigation and debriding system --.

In Claim 4, delete "dispenser" and replace it with the phrase -- wound irrigation and debriding system--.

In Claim 5, delete "dispenser" and replace it with the phrase -- wound irrigation and debriding system--.

In Claim 6, delete "dispenser" and replace it with the phrase --wound irrigation and debriding system--.

In Claim 7, delete "dispenser" and replace it with the phrase -- wound irrigation and debriding system--.

In Claim 8, delete "dispenser" and replace it with the phrase -- wound irrigation and debriding system--.

Examiner objects to Applicants' Amendment of November 16, 2001 on the grounds that it "introduces new matter into the disclosure", namely the word "non-invasive" into the specification. Without agreeing with this conclusion, the Applicants have cancelled the proposed amendment to the specification and the claims.

Applicants submit that the invention, as shown in Figs. 1,3,4 and 6 is clearly non-invasive.

Examiner also interprets claim 1 as claiming a "dispenser" and "not a wound irrigation and debriding system; and to the term "wound irrigation and debriding system" not being positively disclosed in claim 1. Applicants respectfully disagree with this interpretation.

The term "dispenser" does not exclude or conflict with the term "wound irrigation and debriding system" nor are they necessarily mutually exclusive or conflicting. Nevertheless, Applicants have amended claim 1 and its dependent claims for purposes of clarity.

Applicants agree with Examiner that the difference between a one-piece or a multiple piece design is often an obvious design choice. However, not always.

In RE Hubbell 35 CCPA 782, 164 F2d 700, 76 USPQ105, (1947), the Court stated that while, as a general rule, it is not invention to make in one piece what had previously been made in more than one piece, where the article produced is novel, useful and not anticipated, it should be regarded as involving the element of invention.

This rule of law goes back to at least as far as Kementz v. s. Cottle Co., 148 US 556, 37 L. Ed 558, 13 S CT 719 (1893), in which the U.S. Supreme Court held a collar button with a one-piece head and stem was patentable over a multi-piece collar button.

"There is no per se rule that making something in one piece that was formerly made in two or more pieces renders it obvious. Rather, the Court must look beyond the mere fact of unitary construction to determine what improvement results from the one piece construction and whether the improvement or construction itself was obvious from the prior art." Mooney v. Brunswick Corp. 489 F Supp 544, 206 USPQ 121 (1980, ED Wis). Note also Re Larson, 52 CCPA 930, 340 F2d 965, 144 USPQ 347 (1965).

Prior to Applicants' invention, wound irrigation systems came in separately packaged parts as explained in Applicants' application. For lack of a better solution, this is the type of system presently in use. Separate packaging of each element is not just a simple design choice. It is an inherent cause of potential contamination, which is a substantive problem in a hospital environment.

Applicants' invention which is one piece has solved the problem of contamination inherent in prior art systems (multi-parts) as explained in the specifications. Applicants' invention is also more efficient and less costly because it is not multi-part construction.

The phrase "which is disposable in any containers" also is an important and substantive characteristic of the invention because of its structure, i.e., it eliminates the need for a syringe and, hence, the need for Sharps Hazard Disposal systems. Therefore, it allows disposal in any container, and is not confined to the costly, rarer, and regulated Sharps Hazard Disposal systems.

Applicants respectfully traverse the rejection under 35 U.S.C. 102 (b) as being anticipated by Hussey, as to claims 1,3,4, and 5, for the following reasons:

In Schroeder v. Owens-Corning Fiberglas Corp., 514 F2d 901, 185 USPQ 723 (1975, CA 9 Cal.), the court states "An invention is said to be anticipated only if another invention already known or used is identical in substance ` Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a prior art reference there is no anticipation ' (citing Walker v. General Motors Corp. (CA9 Cal) 362 Fed2d 56,58,149 USPQ 472,473,474.)"

Unlike Applicants' invention, Hussey describes an enema unit comprising bottle 10, rectal tip 15 with a break- off tab 20 which, in turn consists of a spherical ball 20 mounted on top of the tip so as to completely enclose the circular passage through the tip, in an attempt to prevent any contamination or spillage of the fluid. The ball is removed

by twisting it. The tip is coated with a lubricant. A sleeve 30 is slid over the tip and heat-shrunk so as to protect the lubricant on the tip from contamination (col.3, lines 1-26). The lubricant is needed precisely because of the nature of an enema. It is inherently intrusive.

Applicants' invention is a wound irrigation and debriding system. It does not require lubricating the nozzle as it is not intrusive. In fact, Applicants' nozzle, as shown in Figs. 1,3,4, and 6 could not safely function as an enema tip. Applicants solve the problems of preventing contamination, tampering, and spillage by a single-unit apparatus, which includes a tip at the end of the nozzle around which is wrapped a protective band. Applicants tip is not for rectal insertion and would not work as an enema, it has no break-off tab, no spherical ball. Applicants respectfully suggest that the lubricant coated tip and the closure system patented by Hussey, requiring a break-off tab, a twist-off ball, and a heat-shrunk sleeve is so substantially different from Applicants wound irrigation system as not to anticipate under §102 (b).

Hussey's system requires a more complicated tip and protective sleeve for the lubricant precisely because it is an invasive enema, not the wound irrigation system of Applicants. Hussey's enema unit is in a different art field than Applicants' wound irrigation system. Applicants' invention is concerned not just with sterility of solution, but with rapid delivery and simple disposability without the requirements of Sharps Hazards regulations.

As to claims 3, 4, and 5, Applicants have previously, in a response dated 01/15/00, stated that these claims do not in and of themselves, constitute patentably distinct species. Applicants have never claimed these as separately patentable species. However, these variations cannot be evaluated alone but as a further limitation of claim 1 on which they rely and with which they merge as dependent claims.

Claim 2 has been rejected under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Reddick. This rejection is respectfully traversed for the reasons noted below.

If, as Applicants contend, Hussey does not anticipate Applicant's invention since Hussey does not contain each and every limitation of Applicants' invention, then it should be immaterial whether Reddick's filters would have been obvious to modify Hussey.

Applicants do not claim the use of a filter in their invention as novel per se. Rather, dependent claim 2 incorporates all of the elements of independent claim 1, adding the filter as a further limitation. Within this context, Applicants contend that selectively choosing the filters of Reddick's douche apparatus to add to Hussey's enema unit does not constitute the obviousness of Applicant's invention. Applicants respectfully suggest that Hussey's enema, even with Reddick's filter, would not make it obvious to constitute Applicants' wound irrigation and debriding system. Such a combination would simply not work.

Likewise, claim 6 is rejected under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Rose. Rose describes and claims a nasal douche , which is inserted "snugly into the nostril". (Line 40.) Here, again, Applicants have never claimed that the angle of their nozzle is per se patentable. Dependent claim 6 must be read as a limitation on claims, not as novelty per se. Applicants repeat and reaffirm all of the same arguments against a finding of obviousness over their invention as they did for the previous reference of Reddick in view of Hussey, except that the argument here refers to angled nozzles rather than filters.

Examiner rejects claims 7 and 8 under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Wallace et al. Applicants agree with Examiner that Hussey does not disclose a dispenser having a sterile solution containing sodium chloride and/or distilled water. Hussey describes and claims an enema. Wallace et al describes and claims polymeric compositions and methods. One means of delivering the hydrogel of the Wallace invention is a syringe. (See, for example, Figs. 1, 2A, 3A.) Applicants do not claim a syringe.

Applicants respectfully disagree with Examiner's position that claims 7 and 8 are rendered obvious in view of these two references. Applicants also respectfully disagree that the enema system of Hussey would be an obvious alternative to Applicants' dispenser, considering the totality of Applicants' wound irrigation and debriding system.

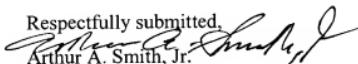
Nevertheless, Applicants are not claiming the sterile solutions of claims 7 and 8 as patentable per se. They do assert, however, that the entire invention as claimed, taken in its entirety is patentable, when the dependent claims are read in conjunction with the independent claim.

Applicant's invention addresses the needs of the medical art dealing with wound irrigation and debriding, particularly under emergency conditions, where time is of the essence, sterility of the unit is essential, and disposability and economy is important.

As further evidence of patentability, Applicants append the affidavits of Kristn Lavoie, RN, CWON, (Ex. A); and Tomas D. Divinagracia, MD, General Surgeon (Ex.B).

For all of the reasons explained above and in the previously filed substantive response, Applicants respectfully suggest this case is in condition for allowance.

In the event that Examiner does not agree or has questions or concerns, Applicants request an interview.

Respectfully submitted,

Arthur A. Smith, Jr.

Reg. No. 24,178
P.O. Box 130016
Boston, MA 02113

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REPLACEMENT PAGE FOR THE JANUARY 27, 2003 AMENDEMENT TO
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The replacement for claims 1 through 8 is as follows:

1. A one piece sterile wound irrigation and debriding system, comprising:
a flexible chamber having an internal volume containing a sterile solution, said chamber having an orifice at one end thereof;
a nozzle having a first opening at one end and a second opening at the other end thereof, wherein said first opening is affixed to said orifice of said chamber; and said second opening dispenses said solution;
a protective tip affixed to said second opening of said nozzle, thereby maintaining said solution in a sterile state; and
a removable packaging band around said protective tip.
2. The wound irrigation and debriding system of claim 1 wherein said nozzle contains a filter at said first opening.
3. The wound irrigation and debriding system of claim 1 wherein said nozzle has a screw-on cap affixing said first opening to said orifice of said chamber.
4. The wound irrigation and debriding system of claim 1 wherein said nozzle is molded to said chamber.
5. The wound irrigation and debriding system of claim 1 wherein said nozzle is angled.
6. The wound irrigation and debriding system of claim 1 wherein said nozzle is straight.
7. The wound irrigation and debriding system of claim 1 wherein said sterile solution contains 0.9 percent USP sodium chloride.
8. The wound irrigation and debriding system of claim 1 wherein the said sterile solution contains 0.9 percent distilled water.